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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,628	11/23/2001	E. James Squires	6580-234	8447

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MCKEE, VOORHEES & SEASE, P.L.C.
801 GRAND AVENUE
SUITE 3200
DES MOINES, IA 50309-2721

EXAMINER

STEADMAN, DAVID J

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 12/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/024,628

Applicant(s)

SQUIRES ET AL.

Examiner

David J Steadman

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 7-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>11/29/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

[1] Applicants' amendment to the claims and specification, filed October 27, 2004, is acknowledged.

[2] Applicants' amendment to the claims and specification, filed November 10, 2004, is acknowledged. Applicants state in this amendment that the amendment "is a duplicate of the Amendment which was filed" October 27, 2004, "with the exception that Applicants have amended the title of the application and included a new oath" (see page 9, top of the response filed November 10, 2004). As such, the listing of the claims filed November 10, 2004 replaces all prior versions and listings of the claims.

[3] Receipt of a substitute oath or declaration, filed November 10, 2004, is acknowledged.

[4] Receipt of a supplemental information disclosure statement, filed November 29, 2004, is acknowledged.

[5] Applicant's arguments filed November 10, 2004 have been fully considered and are deemed to be persuasive to overcome some of the rejections and/or objections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

[6] The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

[7] Claims 1-26 are pending in the application.

Art Unit: 1652

[8] Claims 7-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim.

[9] Claims 1-6 are being examined on the merits.

Claim Objections

[10] The objection to claims 1 and 3-6 in the recitation of "CYP2E1" is maintained for the reasons of record as set forth at item [10] of the Office action mailed July 28, 2004 and for the reasons stated below.

RESPONSE TO ARGUMENT: Applicants argue the objection has been overcome by reciting the phrase for which the abbreviation is used in claim 1. However, no such amendment has been made. As such, the objection is maintained. Appropriate correction is required.

Claim Rejections - 35 USC § 112, Second Paragraph

[11] The rejection of claims 1-6 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "levels" is maintained for the reasons of record as set forth at item [14], part [a] of the Office action mailed July 28, 2004 and for the reasons stated below.

RESPONSE TO ARGUMENT: Applicants argue the rejection has been overcome by amendment to claim 1 to recite "(b) detecting the enzymatic activity or

Art Unit: 1652

protein levels of one or more enzymes.” However, no such amendment has been made.

As such, the rejection is maintained.

[12] The rejection of claims 1-6 under 35 U.S.C. 112, second paragraph, as being unclear in the recitation of “high levels of CYP2E1,” “high levels of a thermostable phenol sulfotransferase,” and “low levels of a glucuronyl transferase” is maintained for the reasons of record as set forth at item [14], part [b] of the Office action mailed July 28, 2004 and for the reasons stated below.

RESPONSE TO ARGUMENT: Applicants argue the claim language, when analyzed in light of the specification, is not unclear or indefinite, citing pp. 7-9 of the specification, which provides “definitions” for the terms at issue. Applicants' argument is not found persuasive.

MPEP 2111 directs the examiner to provide claims their broadest reasonable interpretation in light of the specification. While it is proper to use the specification to interpret what applicant meant by a word or phrase recited in a claim, it is not proper to read limitations appearing in the specification into the claim when these limitations are not recited in the claim. In each of the term definitions, it is noted that the levels of CYP2E1, sulfotransferase, or glucuronyl transferase are all compared to a “suitable control.” While the specification provides non-limiting examples of what a “suitable control” is meant to encompass by reciting “[s]uitable controls include female pigs and male pigs that are known to have boar taint.” However, there is no indication that a “suitable” control is meant to be limited to female pigs and male pigs that are known to have boar taint. In other words, while the specification indicates that a “suitable control”

Art Unit: 1652

includes female pigs and male pigs that are known to have boar taint, is the scope of "suitable" controls limited to female pigs and male pigs that are known to have boar taint? As such, it is unclear from the specification as to the scope of "suitable" controls that are to be used as a reference to determine whether the sample from the male pig has relatively high, low, or equivalent levels of CYP2E1, a thermostable phenol sulfotransferase and/or a glucuronyl transferase.

[13] The rejection of claims 1-6 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "a thermostable phenol sulfotransferase" is maintained for the reasons of record as set forth at item [14], part [c] of the Office action mailed July 28, 2004 and for the reasons stated below.

RESPONSE TO ARGUMENT: Applicants argue the specification, at p. 11, states that thermostable and thermolabile sulfotransferase differ in their properties and that at pp. 11 and 40, states that a thermostable phenol is sensitive to inhibition by DCNP and PCP, whereas a thermolabile phenol sulfotransferase is resistant to inhibition by DCNP and PCP. Applicants argue that based on these differences, a skilled artisan would be able to distinguish between a thermostable and a thermolabile phenol sulfotransferase. Applicants' argument is not found persuasive.

The examiner has reviewed pp. 11 and 40 of the specification filed November 23, 2001 and cannot locate applicants' cited disclosure. The examiner can find no disclosed characteristics that would clearly distinguish the scope of recited thermostable phenol sulfotransferase from those polypeptides considered to be thermolabile phenol sulfotransferases. Also, it is not clear from applicants' arguments as to whether the

Art Unit: 1652

specification clearly defines a thermostable phenol sulfotransferase as being sensitive to inhibition by DCNP and PCP, while a thermolabile phenol sulfotransferase is resistant to inhibition by DCNP and PCP, or if this is merely provided as an exemplary characteristic. As such, it is unclear as to how heat stable a phenol sulfotransferase must be to be included within the scope of the claims.

[14] The rejection of claims 1-6 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of “[a] method” is maintained for the reasons of record as set forth at item [14], part [d] of the Office action mailed July 28, 2004 and for the reasons stated below.

RESPONSE TO ARGUMENT: Applicants argue the claims have been amended to replace “[a] method” with “[t]he method.” However, no such amendment has been made. As such, the rejection is maintained.

Claim Rejections - 35 USC § 112, First Paragraph

[15] The written description rejection of claims 1-6 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record as set forth at item [15] of the Office action mailed July 28, 2004 and for the reasons stated below.

RESPONSE TO ARGUMENT: Applicants argue the specification describes specific chemical properties and common attributes of the genus of recited sulfotransferases and glucuronyl transferases that are associated with skatole such that a skilled artisan could identify the species belonging to the genus by these properties and attributes. Applicants' argument is not found persuasive.

Art Unit: 1652

As an initial matter, it is noted that the description of the genus of cytochrome P4502E1 (CYP2E1) enzymes is not at issue as it is the examiner's position that the genus of CYP2E1 enzymes as detected by the claimed method has been adequately described by the specification. The specification discloses a nucleic acid sequence encoding pig CYP2E1 (p. 12), discloses at least two CYP2E1 specific inhibitors, chlorzoxazone and diallylsulfide (DAS) (p. 8 and 33), and discloses a commercially available kit for measuring levels of CYP2E1 by Western blotting (p. 29). In view of this disclosure, it is the examiner's position that the specification adequately describes the genus of CYP2E1 enzymes that are measured to determine a male pig's susceptibility to boar taint. In contrast, the specification fails to describe the characteristics that distinguish the recited genera of sulfotransferases and glucuronyl transferases such that a skilled artisan could recognize the members of the respective genus such that one could detect their levels in order to determine the susceptibility of male pig to developing boar taint. Given the lack of description of a representative number of species of sulfotransferases and glucuronyl transferases that are related to a male pig's susceptibility to developing boar taint, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicant was in possession of the claimed invention.

[16] The scope of enablement rejection of claims 1-6 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record as set forth at item [16] of the Office action mailed July 28, 2004 and for the reasons stated below.

RESPONSE TO ARGUMENT: Applicants argue the rejection has been overcome by amendment. Applicants' argument is not found persuasive.

The examiner maintains the position that undue experimentation is required to make and use the full scope of the claims. It is the examiner's position that the specification, while being enabling for a method for determining the susceptibility of a male pig to developing (synthesizing or forming) boar taint comprising: a) obtaining a liver sample from a male pig and b) immunologically detecting the level of CYP2E1 by Western blotting, detecting CYP2E1 enzymatic activity, detecting the rate of glucuronidation of para-nitrophenol or 2-naphthol, or detecting the rate of sulfation of 2-naphthol wherein a high level of CYP2E1, a low rate of glucuronidation of para-nitrophenol or 2-naphthol, or a high rate of sulfation of 2-naphthol as compared to a female control pig or a male control pig or a group of male control pigs indicates that the male pig has a reduced susceptibility to developing boar taint, does not reasonably provide enablement for the methods as encompassed by claims 1-6. The examiner's position is supported by the detailed analysis of the Factors of *In re Wands* as set forth at pp. 10-12 of the Office action mailed July 28, 2004 and incorporated herein.

Conclusion

[17] Status of the claims:

- Claims 1-26 are pending.
- Claims 7-26 are withdrawn from consideration.
- Claims 1-6 are rejected.

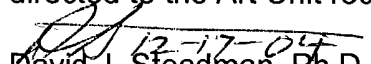
Art Unit: 1652

- No claim is in condition for allowance.

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (571) 272-0942. The Examiner can normally be reached Monday-Friday from 7:00 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The FAX number for submission of official papers to Group 1600 is (703) 872-9306. Draft or informal FAX communications should be directed to (571) 273-0942. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.


David J. Steadman, Ph.D.
Patent Examiner
Art Unit 1652